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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/798,766	03/11/2004	Francois Maltais	2004993-0011 (VPI/03-101)	8361
27916 7590 01/14/2008 VERTEX PHARMACEUTICALS INC. 130 WAVERLY STREET CAMBRIDGE, MA 02139-4242			EXAMINER KOSACK, JOSEPH R	
			ART UNIT 1626	PAPER NUMBER
			MAIL DATE 01/14/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

10/798,766

Applicant(s)

MALTAIS ET AL.

Examiner

Joseph Kosack

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 15 November 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1,7-12,14,15,17 and 18 is/are pending in the application.
- 4a) Of the above claim(s) 8,15,17 and 18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,7,9-12 and 14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Claims 1, 7-12, 14-15, and 17-18 are pending in the instant application.

#### ***Amendments***

The amendment filed on November 15, 2007 has been acknowledged and has been entered into the application file.

#### ***Election/Restrictions***

Applicant is reminded that as per MPEP 803.02, when a provisional election of species is found to be unpatentable, then the provisional election will be given effect. However, if and when the elected species is found to be allowable, the search will be expanded to include additional species. Applicant has stated that a complete search has been done on the corresponding PCT application. This is immaterial because applications go through a different restriction practice internationally and are not restricted based on the independent and distinct standard. Therefore, until the elected species is found to be patentable, the search will *not* be expanded.

#### ***Previous Claim Objections***

Claims 1-7, 9-12, and 14 were previously objected to for containing elected and non-elected subject matter. As non-elected subject matter is still in the claims, the objection is maintained. Applicant is reminded that once the elected species is found to be allowable, the scope of elected subject matter will be expanded to cover additional species. The objection is withdrawn for claims 2-6 as those claims have been cancelled.

#### ***Previous Claim Rejections - 35 USC § 103***

Claims 1-7 and 9-12 and 14 were previously rejected under 35 U.S.C. 103(a) as being obvious over Cao et al. (WO 2002/64586) in view of In re Wood (199 USPQ 137).

Applicant has traversed the rejection on the grounds that the prior art has not shown the modification to be made and that there are three distinct changes from the compound of the prior art.

This is not found to be persuasive in that hydrogen and methyl have been held to be obvious variants by the courts such as the decision of In re Wood. Also, the basis of that decision was that compounds of similar structure would behave similarly. Applicant has not provided any evidence of secondary considerations that would rebut the presumption that the compounds would behave similarly. Applicant has cited Takeda v. Alphapharm, however that case does not deal with hydrogen and methyl as obvious variants but involves homologization and ringwalking. Therefore, the rejection must be maintained for claims 1, 7, 9-12, and 14. The rejection of claims 2-6 is withdrawn as those claims are cancelled.

#### ***Previous Double Patenting Rejections***

Claims 1-7 and 9-14 were previously rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2 and 22-23 of U.S. Patent No. 6,743,791 in view of In re Wood (199 USPQ 137).

Additionally, claims 1-7 and 9-14 were previously provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 20 and 41-42 of copending Application No. 10/770,814, published as US-PGPUB

2004/0229875 A1 in view of In re Wood (199 USPQ 137) and Patani et al. (*Chemical Reviews* 1996, 3147-3176).

The terminal disclaimer has been approved and the above rejections are withdrawn.

Claims 1-7 and 9-14 were previously provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 22-23 of copending Application No. 11/128,870, published as US-PGPUB 2006/0106069 A1 in view of In re Wood (199 USPQ 137) and Patani et al. (*Chemical Reviews* 1996, 3147-3176).

Applicant's arguments have been considered, and have been found to be persuasive. The provisional rejection is withdrawn.

### ***Claim Objections***

Claims 1, 7, 9-12, and 14 are objected to for containing elected and non-elected subject matter. The elected subject matter have been identified supra.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

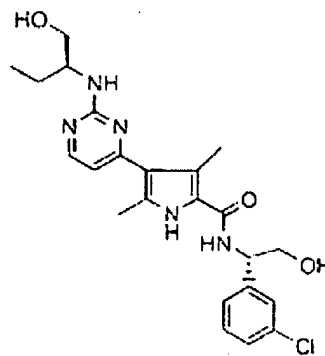
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

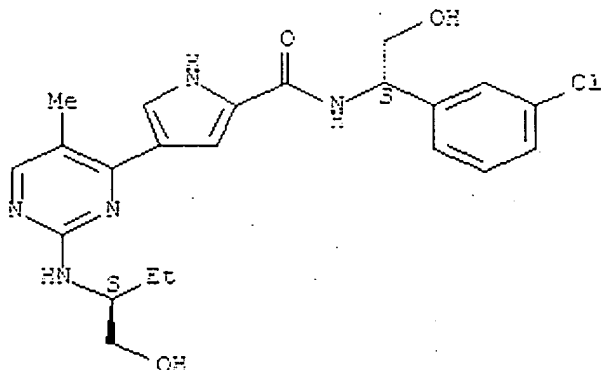
Claims 1, 7, 9-12, and 14 rejected under 35 U.S.C. 103(a) as being obvious over Cao et al. (WO 2002/64586) in view of In re Wood (199 USPQ 137).



The instant invention is drawn to the compound and its pharmaceutical composition.

Determination of the scope and content of the prior art (MPEP §2141.01)

Cao et al. teach a compound of the formula



See Example 232, page 137. Cao et al.

also teaches pharmaceutical compositions including the antiproliferative drug taxol.

See pages 20-28.

Ascertainment of the difference between the prior art and the claims (MPEP

§2141.02)

Cao et al. do not teach a hydrogen in the 5 position of the pyrimidine ring or methyl groups on the unsubstituted carbons of the pyrrole ring.

Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)

Hydrogen and methyl are deemed obvious variants. In re Wood, 199 USPQ 137

Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to follow the synthetic scheme of Cao et al. and substitute methyl for hydrogen where needed in the pyrimidine and pyrrole rings to make the claimed invention with a reasonable expectation of success. The motivation to do so is provided by Cao et al. Cao et al. teach the use of the synthesized compounds and compositions to treat cancer. See column 10, line 5 through column 13, line 50.

Thus, the claimed invention as a whole was *prima facie* obviousness over the combined teachings of the prior art.

**Conclusion**

Claims 1, 7, 9-12, and 14 are rejected. Claims 1, 7, 9-12, and 14 are objected to.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Kosack whose telephone number is (571)-272-5575. The examiner can normally be reached on M-F 6:30 A.M. until 4:00 P.M. The examiner has every other Friday off.

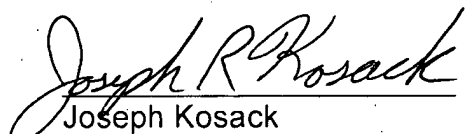
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571)-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

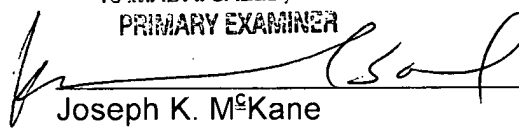


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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
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Art Unit 1626

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